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October 5, 2000

Dockets Management Branch (HFA-305)
US Food Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

To Whom It May Concern:

I am writing to oppose the proposed change in classification from Class III to Class II for totally implantable spinal cord stimulators. I learned of this proposed change from a colleague in pain medicine. I am opposed to this change in classification for two reasons: The first and most important has to do with patient safety. I implant a large number of these systems and have been doing so for the last fifteen years. Whereas they are safe, they are safe because of the rigorous work that has been done by the parent industry and the scrupulous standards established by the FDA. The region of the body and the potential for injury that could be catastrophic, however, in my opinion, mitigates against changing the classification as you have proposed. Very minor changes in design can have a significant impact on safety and I think that any product that is to be implanted, particularly in this area of the body, should be held to exactly the same standard for approval. I can elaborate on this if you wish, but my purpose in writing is simply to ask that you reconsider, or at the very least extend the comment period.

The second reason that I am opposed to this classification has to do with my experience for thirteen years as Chairman of an academic anesthesiology department wherein I have seen the technological frontier in monitoring design largely come to a standstill because of this type of "established technology" classification system. What I mean by this is that in the field of monitoring, it is much easier for a company to rely on established technology than to advance the technological boundary. This type of classification system you propose definitely inhibits innovation in the field. I can bring examples to you if you wish, but for this reason as well, I strongly oppose this change in classification. The field of neuromodulation is just at the beginning in my estimation, and this definitely applies to spinal cord stimulation. By making this change, I think that you will be dramatically inhibit the competition that would otherwise advance the field at a much faster pace.

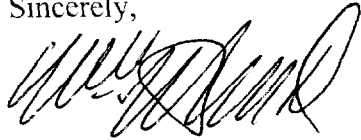
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C/S

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Thank you for your consideration of this request for reconsideration and/or extension of the comment period.

Sincerely,

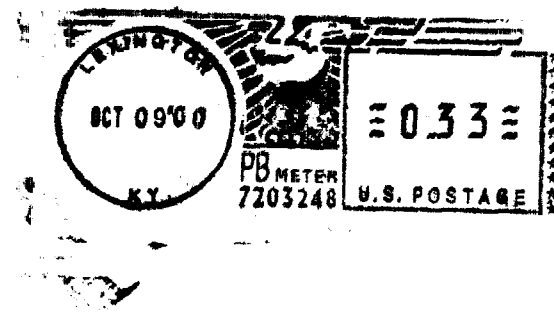
A handwritten signature in black ink, appearing to read 'Witt', with a large, stylized loop at the end.

William O. Witt, MD
Chairman Emeritus, Anesthesiology
Professor, Anesthesiology & Neurosurgery
Director, Pain Management Center

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